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NOV 1 1996

Heelbo, Inc.

Pullover Poncho and Pullover Poncho with Pocket

510(k) Summary**1. Submitter's name, Address and Contact Person****Submitter**Heelbo, Inc.
1134 N. Homan
Chicago, IL 60651**Contact Person**Joseph S. Tokarz, Manager, Regulatory Affairs
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Date Summary Prepared - October 30, 1996

2. Name of Device:

Heelbo Pullover Poncho and Pullover Poncho with Pocket

3. Name of Predicate Device(s)

Heelbo Pullover Poncho and Pullover Poncho with Pocket

4. Description of Device

The Heelbo Pullover Poncho and Pullover Poncho with Pocket are poncho-style safety vests. The Heelbo Pullover Poncho and Pullover Poncho with Pocket are intended to help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair. The Heelbo Pullover Poncho's are also intended to limit the patient's movement while lying on a bed and to prevent the patient from falling out of bed or climbing over the side rails. The Heelbo Pullover Poncho has two straps that secure to the bed frame, wheelchair or geri-chair frame while the Pullover Poncho with Pocket has four straps that secure the bed frame, wheelchair or geri-chair frame. The Pullover Poncho with pocket provides the patient with a pocket to put personal items in.

Both Heelbo Poncho restraints are available in a poly/cotton blend or a polyester mesh material and are available in five sizes to accommodate a wide range of patients. Both styles of pullover poncho are machine washable for continued use.

The following chart shows product availability:

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Heelbo, Inc.**Pullover Poncho and Pullover Poncho with Pocket**

Size of Vest	Material	Color
x-small	Poly/Cotton blend	White
small	Poly/Cotton blend	Yellow
medium	Poly/Cotton blend	Blue
large	Poly/Cotton blend	Green
x-large	Poly/Cotton blend	Beige
x-small	Polyester Mesh	White bias on white breezewear
small	Polyester Mesh	Yellow bias on white breezewear
medium	Polyester Mesh	Blue bias on white breezewear
large	Polyester Mesh	Green bias on white breezewear
x-large	Polyester Mesh	Beige bias on white breezewear

5. Statement of Intended Use

The Heelbo Pullover Poncho and Pullover Poncho with Pocket are intended to help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair. The Heelbo Pullover Poncho's are also intended to limit the patient's movement while lying on a bed and to prevent the patient from falling out of bed or climbing over the side rails.

6. Statement of Technological Characteristics of the Device

The Heelbo Pullover Poncho and Pullover Poncho with Pocket are poncho-style safety vests. The Heelbo Pullover Poncho and Pullover Poncho with Pocket are intended to help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair. The Heelbo Pullover Poncho's are also intended to limit the patient's movement while lying on a bed and to prevent the patient from falling out of bed or climbing over the side rails. The Heelbo Pullover Poncho has two straps that secure to the bed frame, wheelchair or geri-chair frame while the Pullover Poncho with Pocket has four straps that secure the bed frame, wheelchair or geri-chair frame. The Pullover Poncho with pocket provides the patient with a pocket to put personal items in.

The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints dated December 1995.

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7. Biocompatibility Assessment

The subject devices are identical in components materials to the predicate devices. The suppliers of the materials used in the fabrication of these devices have stated that there is a history of safe use of their materials in the clothing and garment industry. In addition, Heelbo, Inc., is not aware of any reports or complaints of skin irritation associated with these materials.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Heelbo Pullover Poncho and Pullover Poncho with Pocket are safe and effective for their intended use and are substantially equivalent to the predicate devices.